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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,030	12/27/2005	Jae Yong Han	50413/008001	7843

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EXAMINER	
WILSON, MICHAEL C	
ART UNIT	**PAPER NUMBER**
1632	

NOTIFICATION DATE	DELIVERY MODE
01/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/554,030	HAN ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,8-11 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,8-11 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 11-1-07 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3-7 and 12-17 have been canceled. Claims 18-21 have been added. Claims 1, 2, 8-11 and 18-21 are pending and under consideration.

Claim Objections

The preamble of claim 1 is objected to because it can be written more clearly as: a method of improving the germline transmission efficiency of chicken primordial germ cells (PGCs). The amount of the efficiency should be in the body of the claim — wherein efficiency of germline transmission of the PGCs injected is 49.7%--.

Claim 2 is objected to because it can be written more clearly as: a method of improving germline transmission when preparing a chicken germline chimera. The amount of the efficiency should be in the body of the claim — wherein efficiency of making germline chimeras is 49.7%--.

The phrase "whereby the chicken germline chimera is prepared" can be more clearly written as –such that a chicken germline chimera occurs--.

The injection phrase at the end of claims 1 and 2 can be incorporated into the injecting step to be clearer. The injecting step should be – injecting said cultured PGCs into the dorsal aorta of a recipient chicken embryo.

Claim 18 is actually limiting the chicken embryonic gonad in claims 1 and 2 and can be written more clearly as --wherein the chicken embryonic gonad is a Korean Ogol chicken (KOC) embryonic gonad.--

Claim 19 is actually limiting the recipient chicken embryo in claims 1 and 2 and can be written more clearly as --wherein the recipient chicken embryo is a White Leghorn embryo.--

Claim 20 limits the chicken embryonic gonad and recipient chicken embryo in claims 1 and 2 and can be written more clearly as --wherein the chicken embryonic gonad is a Korean Ogol chicken (KOC) embryonic gonad and the recipient chicken embryo is a White Leghorn embryo.--

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1, 2, 8-11 remain and 18-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for injecting a chicken embryo, does not reasonably provide enablement for injecting any embryo. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Stable transfection of PGCs in culture and making a transgenic germline chimeric avian

The rejection regarding claim 3 and using genetically altered PGCs to make transgenic chickens has been withdrawn because the claim has been canceled.

The breadth of avian

The rejection regarding the breadth of avian has been withdrawn in part because the claims have been mostly limited to chicken PGCs and making chimeric chickens. The injecting step still encompasses any recipient embryo and is rejected for reasons of record. Limiting the embryo to a chicken embryo would overcome this rejection. Claims 18-21 should also be limited to a recipient chicken embryo.

Indefiniteness

Claims 1, 2, 8-11 remain and claims 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The previous rejections are obviated in view of the amendment and in lieu of the following rejections:

Claim 1 is indefinite because it is drawn to a method of improving the germline transmission efficiency of chicken PGCs by how they are isolated and cultured; however, the claim also comprises a step of injecting the PGCs into a recipient embryo, which is not the basis of the improvement. With the injection step, claim 1 is a method of improving the ability to make germline chimeric chickens, not merely improving the germline transmission efficiency of PGCs as claimed.

Claims 1 and 2 are indefinite because "an improved germline transmission efficiency of up to 49.7%" is unclear. It is unclear if efficiency is increased to 49.7% or if efficiency is increased up 49.7% (49.7% plus that of "normal" efficiency). Efficiency is measured as a percentage – 10 out of 100 embryos showed germline transmission,

which is 10% efficiency. It is unclear if applicants are claiming the efficiency or the increase in efficiency.

Claims 1 and 2 are unclear because the "wherein..." clauses at the end of the claim actually limit step b in the middle of the claim making the claim unclear. In particular, "said PGCs that are in vitro cultured in step (b)" lacks antecedent basis. The "wherein said PGCs... ...express SSEA-1" is indefinite because it is unclear if the PGCs put into culture are positive for SSEA-1, if the cells put into culture are positive for SSEA-1 for at least 10 days or if the cells are positive for SSEA-1 after 10 days. The phrase regarding injecting the cultured PGCs is indefinite because it is unclear if the "cultured PGCs" injected are cells in the 10 day culture (of any age) or if they are PGCs cultured for 10 days. The limitation of culturing the PGCs with gonadal stromal feeder cells should be in the culturing step b. Overall, the claims do not clearly set forth the structure of the cells that are SSEA-1 or what cells are injected.

Claim 21 is indefinite because "the separation of PGCs" lacks antecedent basis in claim 1.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 2 and 8-11 under 35 U.S.C. 102(b) as being anticipated by Chang (Cell Biology International, 1997, Vol. 21, No. 8, pg 495-499) has been withdrawn because Chang did not teach culturing the PGCs for at least 10 day (previous claim 7, now claims 1 and 2).

The rejection of claims 1, 2 and 8 under 35 U.S.C. 102(b) as being anticipated by Park (Mol. Reproduction and Development, 2000, Vol. 56, pg 475-482) has been

withdrawn because Park did not teach culturing the PGCs on a gonadal stroma feeder cell layer.

The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Kim (Transgenic Research, February 2002, Vol. 11, No. 1, pp. 85; presented to the public at the Transgenic Animal Research Conference. Tahoe City, California, USA. September 09-13, 2001) has been withdrawn because Kim did not teach culturing the PGCs on a gonadal stroma feeder cell layer.

The rejection of claims 1, 8 and 10 under 35 U.S.C. 102(b) as being anticipated by Zandong (Transgenic Research, February 2002, Vol. 11, No. 1, pp. 85; presented to the public at the Transgenic Animal Research Conference. Tahoe City, California, USA. September 09-13, 2001) has been withdrawn because Zandong did not inject the PGCs into the dorsal aorta of a recipient embryo.

Claims 1, 2 and 8-11 remain rejected under 35 U.S.C. 102(a) as being anticipated by Han (Theriogenology, Nov. 2002, Vol. 58, pg 1531-1539).

Han isolated PGCs from gonads of stage 28 chicken embryos and cultured them on gonadal stromal feeder cells with bovine serum, SCF, LIF, bFGF, IL-11 and IGF for two months (pg 1532, 2.1). The PGCs stained with SSEA-1 (pg 1533, 2.2). The PGCs were injected into the blood vessel of a recipient embryo (pg 1533, 2.3). Four individuals were germline chimeras (pg 1536, 3.3). The method of Han inherently resulted in germline transmission efficiency of 49.7% as claimed because the method steps of Han are the same as those claimed and described by applicants.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 8-11 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (Transgenic Research, February 2002, Vol. 11, No. 1, pp. 85; presented to the public at the Transgenic Animal Research Conference. Tahoe City, California, USA. September 09-13, 2001) in view of Chang (Cell Biology International,

1997, Vol. 21, No. 8, pg 495-499), Zandong (Transgenic Research, February 2002, Vol. 11, No. 1, pp. 85; presented to the public at the Transgenic Animal Research Conference. Tahoe City, California, USA. September 09-13, 2001) and Han (Theriogenology, Nov. 2002, Vol. 58, pg 1531-1539).

Kim produced germline chimeric chickens by transfer of cultured gPGCs from the embryonic gonad of Korean Ogol Chicken (KOC) into recipient White Leghorn (WL) embryos. Gonadal PGCs were isolated from KOC embryonic gonads at stage 27 (5.5-day-old) and cultured in vitro for 10 days. Approximately 200 cultured gPGCs were injected into the bloodstream through the dorsal aorta of stage 13-14 (2-day-old) recipient embryos. The recipient embryos were incubated until hatching. The recipients were mated with KOC. Donor-derived offsprings were determined as germline chimeric chickens based on their feather color. The method described by Kim inherently provided up to 49.7% efficiency in germline transmission as claimed because Kim taught the germline chimerism efficiency was improved and because the phrase "up to 49.7% efficiency" encompasses any improvement in efficiency up to 49.7%. Furthermore, the method described by Kim is the same as the method of claims 1 and 2 except that Kim did not teach using gonadal stromal feeder cell layer. It is not readily apparent that the use of gonadal stromal feeder cells alone increases germline transmission efficiency to 49.7%.

While Kim did not teach culturing PGCs on a gonadal stromal feeder cell layer, it was well known in the art at the time of filing that PGCs isolated from chicken embryonic gonad were cultured in gonadal stromal feeder cells as exemplified by Chang, Zandong

and Han. Chang used fetal bovine serum, IGF, FGF and LIF. Zandong used medium comprising SCF and LIF. Han used medium comprising fetal bovine serum, SCF, LIF, bFGF, IL-11 and IGF. The media used by Chang, Zandong and Han meet the limitations of claims 8-11.

Thus, it would have been obvious to those of ordinary skill in the art at the time the invention was made to culture the PGCs described by Kim on gonadal stromal feeder cell layer. Those of ordinary skill would be motivated to use any method of culturing PGCs described in the art including on a gonadal stromal feeder cell layer as described by Chang, Zandong and Han. The combined teachings of Kim taken with Chang, Zandong or Han is the same as the method of claims 1 and 2 which inherently results in germline transmission efficiency of 49.7% as claimed.

Thus, Applicants' claimed invention as a whole is *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Patent Examiner